

ANEC proposal on a
Barium limit value for toys
2011-02-25

Background

The limits for barium in the revised Toy Safety Directive (2009/48/EC) are as follows:

- in scraped-off toy material: 56000 mg/kg toy
- in liquid or sticky toy material: 1125 mg/kg toy
- in dry, brittle, powder-like or pliable toy material: 4500 mg/kg toy

This constituted a considerable increase compared to existing limits contained in EN 71-3:

- general limit (for toys defined in clause 1): 1000 mg/kg toy
- modelling clays, finger paints: 250 mg/kg toy

The limit was based on a TDI value (0,6 mg/kg body weight) suggested by RIVM¹ using a TDI derived by the US Agency for Toxic Substances and Disease Registry (ATSDR) in 2005.

Appropriateness of TDI

After finalisation of the RIVM report ATSDR published an update (2007) and reduced the limit by a factor of 3 taking into account the uncertainty of the data base (0,2 mg/kg).

However, as a matter of fact the International Programme on Chemical Safety (IPCS) – a joint venture of WHO, ILO and UNEP - published a so-called "Concise International Chemical Assessment Document (CICAD) on barium in 2001:

<http://www.inchem.org/documents/cicads/cicads/cicad33.htm>

¹ Chemicals in Toys - A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM/SIR Advisory Report 0010278A01. August 2006

The main conclusion of this document:

"The critical end-points in humans for toxicity resulting from exposure to barium and barium compounds appear to be hypertension and renal function. Using a no-observed-adverse-effect level (NOAEL) in humans of 0.21 mg barium/kg body weight per day, a tolerable intake value of 0.02 mg/kg body weight per day for barium and barium compounds has been developed in this document".

Apparently this TDI is a factor of 30 lower than the TDI used by RIVM and a factor of 10 lower than the ATSDR 2007 value although the source documents (studies) were the same in all cases.

It should be noted that WHO based its barium limit for drinking water (WHO Guidelines for Drinking-water Quality, 3rd edition, 2008) on the same NOAEL:

http://www.who.int/water_sanitation_health/dwq/chemicals/barium/en/

Last but not least: the Commission Regulation on plastic materials and articles intended to come into contact with food (10/2011) establishes a barium limit of 1 mg/kg food or food simulant. This limit is related to the daily ingestion of a 60 kg adult corresponding to 0,0166 mg/kg body weight – roughly the same value as used by WHO.

ANEC conclusions

It is obvious that the judgement made by WHO is more on the precautionary side and based on a NOAEL from a human study. It is hard to understand why RIVM did not follow the more conservative assessment by IPCS/WHO, the more so as existing European legislation in the field of food contact materials seems to be broadly in line with WHO recommendations.

From this follows that a correction of the barium limits in the TSD is necessary. A reduction of current barium levels by a factor of 30 seems warranted.

ANEC proposes:

The current barium limits in the TSD should be changed as follows:

- in scraped-off toy material from 56000 mg/kg to 1867 mg/kg
- in liquid or sticky toy material from 1125 mg/kg to 37 mg/kg
- in dry, brittle, powder-like or pliable toy material from 4500 mg/kg to 150 mg/kg.

END.

About ANEC

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